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Chewing gum vs. ibuprofen in the management of orthodontic pain, a multi-centre randomised controlled trial – the effect of anxiety

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ABSTRACT

Objectives: Pain is a common side effect of orthodontic treatment. An objective of this study, part of a large previously reported RCT on pain and analgesic use, was to determine the effect of anxiety on perceived pain and use of analgesia.

Methods: 1000 patients aged 11–17 years, undergoing upper and lower fixed appliance treatment in nine hospital departments were recruited into this two-arm parallel design randomised controlled trial. One arm was given sugar-free chewing gum and the other arm ibuprofen for pain relief. Neither the clinicians nor patients were blinded to assignment. In addition to recording pain experience and analgesic use for 3 days following appliance placement and first archwire change, each patient recorded their level of anxiety immediately following the fitting of the appliance and the first archwire change.

Results: 419 chewing gum group (84%) and 407 ibuprofen group (83%) questionnaires were returned following appliance placement, and 343 chewing gum group (70%) and 341 ibuprofen group (71%) questionnaires were returned following the first archwire change. The mean anxiety scores following fitting of the appliance and first archwire change were 2.7 (SD 2.1) and 1.6 (SD 1.8), respectively. There were weak but significant positive associations between anxiety scores and pain scores. Multi-level modelling produced a coefficient for anxiety of 0.23 (95% CI 0.17–0.28) for appliance placement, suggesting a small rise (0.23) on the 11-point pain scale for a one-point increase on the corresponding anxiety scale. Following archwire change, the corresponding coefficient was 0.32 (0.24–0.39). For ibuprofen use, again simple analyses suggested a relationship with anxiety. Multi-level logistic modelling produced an odds ratio for ibuprofen use of 1.11 (95% CI 1.07–1.15) at appliance placement and 1.21 (1.10–1.33) at the first archwire change. There was a 10–20% increase in the odds of using ibuprofen for each one-point increase on the anxiety scale. No such relationship was found between anxiety and chewing gum use. There were no adverse effects or harms reported during the trial. Approvals were granted by the Research Ethics Committee (08/H0106/139), R&D and MHRA (Eudract 2008-005522-36) and the trial was registered on the ISRCTN (79884739) and NIHR (6631) portfolios. Support was provided by the British Orthodontic Society Foundation.

Conclusions: There was a weak positive correlation between anxiety reported and pain experienced following both the initial fitting of the fixed appliances and at the subsequent archwire change. Patients that were more anxious tended to take more ibuprofen for their pain relief.

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Pain; anxiety; fixed orthodontic appliances; analgesics; RCT

Introduction

A frequent side effect of orthodontic treatment with fixed appliances is pain, which usually arises within the first few hours after an orthodontic appliance is fitted or adjusted. This pain may persist for the following 3–5 days (Bradley et al. 2007). The most common intervention for the management of such pain is the use of oral analgesics, for example ibuprofen or paracetamol (Xiaoting et al. 2010), although other methods have been suggested including electrical stimulation (TENS machines) (Roth & Thrash 1986; Weiss & Carver 1994),

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plastic chews (Hwang et al. 1994; Otasevic et al. 2006), tooth vibration (Marie et al. 2003), cognitive behavioural therapy (Wang et al. 2012) and text message follow up (Keith et al. 2013). Interestingly a study on the use of a follow up telephone call reported that the level of perceived orthodontic pain was reduced following the call, but was unaffected by its content, i.e. whether the call was a structured call demonstrating care and reassurance, or an attention-only call merely thanking individuals for participating in the study (Bartlett et al. 2005). This perhaps emphasises the fact that the perception of pain is mediated by complex neural pathways, which are closely related to varying emotional states, including fear and more specifically, anxiety (Suzuki et al. 2004). A limited number of studies have previously shown that anxiety can affect the perception of dental, including orthodontic pain (Bartlett et al. 2005; Bergius et al. 2008; Beck et al. 2014), with more anxious patients generally reporting greater levels of pain. A recent systematic review on dental pain in adolescents and young children found this relationship was more common in girls (Shim et al. 2015). However, it is unknown whether increased anxiety is also related to an increased use of analgesics during or after any dental or orthodontic treatment.

A recent clinical trial into the effect of the use of sugar-free chewing gum on orthodontic pain with fixed appliances, showed that chewing gum use can lead to a reduction in the number of oral analgesics required to manage the pain, but it had no significant effect on the number of appliance breakages (Ireland et al. 2016). As part of this trial the effect of anxiety on reported pain and analgesic usage was also investigated. It is this part of the study that is reported here.

Materials and methods

A randomised controlled clinical trial was performed with the primary outcome being to determine the use of analgesics (ibuprofen or chewing gum) to manage pain on the three days following fixed appliance placement and again following the first archwire change. The methodology and results of this trial have been reported elsewhere (Ireland et al. 2016). At the same time patients were asked to record their levels of anxiety using a Likert scale immediately following the fitting of the appliance and the first archwire change.

This study was a prospective two-arm parallel design multicentre randomised controlled trial with a 1:1 allocation ratio, based in nine hospital orthodontic departments in the UK. The intervention group received chewing gum for pain relief (with ibuprofen as a backup), whilst the control group received ibuprofen only following both initial fixed appliance placement and the first archwire change. In each group the patients were to use the chewing gum (intervention group) and ibuprofen (control group) only if required to control pain. 1000 consecutive patients were invited to take part in the study and the inclusion criteria were, patients should be aged between 11 and 17 years and must be about to have full upper and lower fixed appliances fitted. There was no stipulation as to the type of fixed appliance, aligning wires, type of ligation, malocclusion, number of teeth extracted, or the experience of the orthodontist treating the patients, as this was a pragmatic real-world trial.

The exclusion criteria included patients with a history of:

- Hypersensitivity to ibuprofen or any of the other ingredients
- Hypersensitivity reactions to aspirin or other NSAIDs including asthma, rhinitis or urticaria
- Current or previous peptic ulceration, or bleeding of the stomach
- Severe heart failure

The trial was approved by the Research Ethics Committee (08/H0106/139), R&D and MHRA (Eudract 2008-005522-36) and was registered on the ISRCTN (79884739) and NIHR (6631) portfolios. Patient information leaflets outlining the study were provided to the patients and parents, and written informed consent obtained.

In order to assess the possible effect that anxiety may have on pain perception and analgesic use, in both the experimental and control groups each patient was asked to complete a short anxiety questionnaire immediately following the initial bond up and wire placement and again immediately following the first archwire change. This comprised an 11-point numerical rating scale on which they were asked to rate their current level of anxiety, ranging from no anxiety (0) to worst anxiety possible (10). A brief numerical anxiety scale was selected to enable direct comparison with pain data collected in this study and with other studies that have used similar measures to assess paediatric procedural distress (Cohen et al. 2004). The treating clinician and patients were not blinded to the intervention, but each questionnaire with its unique identifier, once collected, was sent to a central collection centre for the data to be uploaded onto a spreadsheet. The person uploading the data was blinded as to the intervention/control group allocation.

As with the initial pain and chewing gum/ibuprofen use analysis, the data were analyzed using STATA version 14 (STATA Corp, USA) and the analytical approaches reported for the main trial results (Ireland et al. 2016) were used

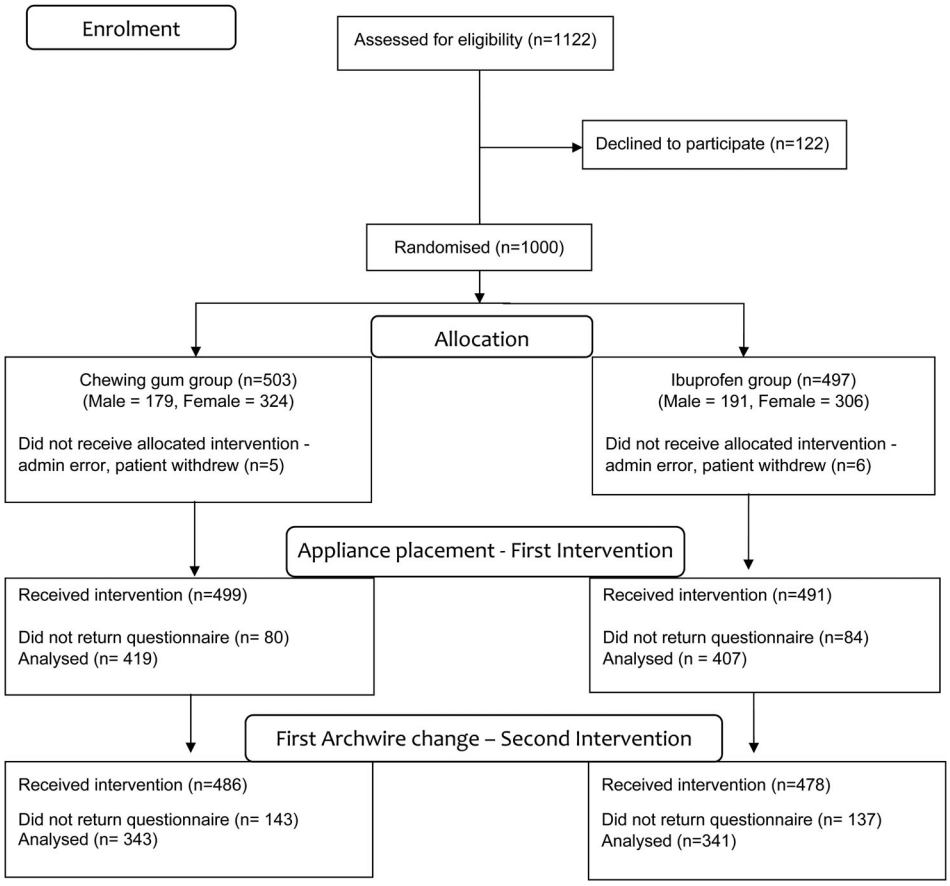

Figure 1. Consort flow diagram.

here, but in this case including anxiety score in the models as a putative predictor. Specifically, multi-level models were fitted with treatment group, time point (and the interaction between treatment group and time point, since this was statistically significant) and anxiety as fixed effects, centre as a random effect and individual (nested within centre) also as a random effect; random effects in both cases were included as intercept terms. Linear models were fitted for pain as an outcome, logistic for ibuprofen use, with separate models at each of the two visits as in the main trial analysis.

Results

419 chewing gum group (84%) and 407 ibuprofen group (83%) questionnaires were returned following appliance placement, and 343 chewing gum group (70%) and 341 ibuprofen group (71%) questionnaires were returned following the first archwire change. Overall, the mean anxiety score was 2.7 (SD 2.1) at initial appliance placement and 1.6 (SD 1.8) at the first archwire change. Fitting the relevant multi-level model for appliance placement produced a coefficient for anxiety of 0.23 (95% CI 0.17–0.28), suggesting a small rise (0.23) on the 11-point pain scale for a one-point increase on the corresponding anxiety scale. Following archwire change, the corresponding coefficient was 0.32 (0.24–0.39).

For ibuprofen use, the multi-level logistic models produced an odds ratio of 1.11 (95% CI 1.07–1.15) at appliance placement and 1.21 (1.10–1.33) at the first archwire change. Thus there was a 10–20% increase in the odds of using ibuprofen for each one-point increase on the anxiety scale. No such relationship was found between anxiety and chewing gum use within the chewing gum group (OR = 0.98 (0.93–1.04)) at appliance placement and (OR = 1.10 (0.97–1.24)) at first archwire change.

Discussion

It is well known that pre-procedural anxiety is related to increased levels of perceived pain for patients undergoing restorative dental treatment, such as periodontal treatment and implant placement (Klages et al. 2006; Fardal & McCulloch 2012). Within orthodontics, Bergius et al. (2008) reported that following the placement of orthodontic separators, patients who scored higher on the Dental Anxiety Scale (DAS) reported higher levels of pain than those with a lower DAS score (Bergius

et al. 2008). What is less clear is whether anxious patients require more analgesia to manage their pain. Experimental work by Tang et al. (2005), looking at pain perception in response to electrical stimulae in two groups of patients, namely low trait anxious (LTA) and high trait anxious (LTA), demonstrated that both groups had the same pain thresholds and yet the more anxious (HTA) patients perceived the electrical stimulus to be more painful. The results of our investigation would suggest a weak, but positive association between reported anxiety and pain at both appliance placement and at the time of the first archwire change. In addition, there was a weak positive relationship between those patients who were more anxious and those who reported greater ibuprofen use. This is perhaps not unexpected if the more anxious patient perceives themselves as experiencing higher levels of pain compared with the less anxious patient, as suggested by Tang et al. (2005). The use of more post-operative analgesia in patients suffering from anxiety and depression has been reported in women undergoing radical mastectomy (Ozalp et al. 2003), with satisfaction with post-operative analgesia being influenced by the state of pre-operative anxiety and depression. In other words, the lower the anxiety and depression, the better the perceived post-operative analgesia. This same effect was not seen with anxiety and chewing gum use in the present study. This may be due to our patients not considering chewing gum to be an analgesic that would help alleviate their orthodontic pain. However, a recent experimental study has demonstrated that gum-chewing reduces stress-related responses and therefore may indirectly affect pain perception and the need for analgesia, by reducing the unwanted effects of anxiety (Konno et al. 2016).

The findings of this trial are generalisable as a result of the large sample size and multicentre design. The principal limitation was the self-reported nature of the results and requirement of the patients to post the pain questionnaires to the trial centre.

Conclusions

1. There was a weak positive association between the level of anxiety reported and the pain experienced, following both the initial fitting of the fixed appliances and at the subsequent archwire change.
2. Patients that were more anxious tended to take more ibuprofen for their pain relief (Figure 1).

Disclosure statement

No potential conflict of interest was reported by the authors.

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